



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: 500 M Street, N.E., Washington, D.C. 20540
Washington, D.C. 20540
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/386,266	08/31/1999	DAVID F. BRAYDEN	99/1080 US	1219

8800 11/29/2002

ELAN HOLDINGS INC
1300 GOULD DRIVE
GAINESVILLE, GA 30504

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
----------	--------------

1645

DATE MAILED 11/29/2002

18

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/386,266

Applicant(s)

Brayden

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 23, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 15-20 ~~is~~/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 15-20 ~~is~~/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15 6) ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicant's Amendment

- 1) Acknowledgment is made of Applicant's amendment filed 09/23/02 (paper no. 17) in response to the non-final Office Action mailed 04/23/02 (paper no. 14).

Status of Claims

- 2) Claims 1 and 15 have been amended via the amendment filed 09/23/02.
Claims 1-6 and 15-20 are pending and are under examination.

Information Disclosure Statement

- 3) Acknowledgment is made of Applicants' Information Disclosure Statement filed 05/10/02 (paper no. 15). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 18).

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

- 6) The rejection of claims 1-4, 6 and 15-18 made in paragraph 13 of the Office Action mailed 06/22/01 (paper no. 8) under 35 U.S.C § 102(b) as being anticipated by Moore *et al.* (*Vaccine* 13: 1741-1749, 1995), is withdrawn in light of Applicant's amendment to the base claims.
- 7) The rejection of claims 1-4, 6 and 15-18 made in paragraph 14 of the Office Action mailed 06/22/01 (paper no. 8) under 35 U.S.C § 102(b) as being anticipated by Nixon *et al.* (*Vaccine* 14: 1523-1530, 1996) as evidenced by Garcon *et al.* (US 6,372,227) or Rook *et al.* (US 6,056,964), is withdrawn in light of Applicant's amendment to the base claims.
- 8) The rejection of claims 1, 5, 15 and 19 made in paragraph 15 of the Office Action mailed 06/22/01 (paper no. 8) under 35 U.S.C § 103(a) as being unpatentable over Moore *et al.* (*Vaccine*

Serial Number 09/386,266

Art Unit: 1645

13: 1741-1749, 1995) in view of Lochter *et al.* (WO 95/28486), is withdrawn in light of Applicant's amendment to the base claims.

9) The rejection of claims 1, 5, 15 and 19 made in paragraph 16 of the Office Action mailed 06/22/01 (paper no. 8) under 35 U.S.C. § 103(a) as being unpatentable over Nixon *et al.* (*Vaccine* 14: 1523-1530, 1996) as evidenced by Rook *et al.* (US 6,056,964) and in view of Jones *et al.* (*Behring Inst. Mitt.* 98: 220-228, February 1997) (Jones, 1997) and Mills *et al.* (*Infect. Immun.* 61: 399-410, 1993, already of record), is withdrawn in light of Applicant's amendment to the base claims.

10) The rejection of claims 1-6 and 15-19 made in paragraph 17 of the Office Action mailed 06/22/01 (paper no. 8) under 35 U.S.C. § 103(a) as being unpatentable over Jones *et al.* (*Vaccine* 14: 675-681, 1996) (Jones, 1996) in view of Nixon *et al.* (*Vaccine* 14: 1523-1530, 1996) and Tice *et al.* (US 6,024,983, already of record) or O'Hagan (*J. Pharm. Pharmacol.* 49: 1-10, 1997, already of record), is withdrawn in light of Applicant's amendment to the base claims.

11) The rejection of claims 15 and 20 made in paragraph 18 of the Office Action mailed 06/22/01 (paper no. 8) under 35 U.S.C. § 103(a) as being unpatentable over Nixon *et al.* (*Vaccine* 14: 1523-1530, 1996) as evidenced by Rook *et al.* (US 6,056,964) and in view of Jones *et al.* (*J. Biotechnol.* 44: 29-36, 1996, already of record), withdrawn in light of Applicant's amendment to the base claim.

New Rejection(s)

Applicants are asked to note the new rejection(s) made in this Office Action. Applicants' amendments necessitated the new ground(s) of rejection presented in this Office Action.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

12) Claims 1-6 and 15-20 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 15, as amended, include the limitation: "at least 50% of the microparticles are at least 0.6 μm and" least 50% of the microparticles are less than 5 μm . Applicants point

to 'Claim 1 vs. Claim 7' as filed and page 5, third paragraph vs. fourth paragraph and state that the central theme of the application is that microparticle populations have properties 'different from those nanoparticles'. Applicants claim that the differences reflect size differences between the two types of populations. Applicants state that the 'claims in the application as filed incompletely reflected the distinction'. Applicants further state that the 'claims set an upper limit (5 μ M) to the median size of a microparticle population, but failed to set a lower limit'. A review of the specification as originally filed shows that there is no descriptive support for the now included microparticle size combination or the two size limits. Contrary to Applicants' assertion, claim 7 is directed to a non-elected subject matter, i.e., a method of inducing a T_{H2} polarised immune response to an antigen, as opposed to the elected subject matter, i.e., a method of inducing a T_{H1} polarised immune response to an antigen. Furthermore, the non-elected claim 7 recites at least 50% of 'nanoparticles' (as opposed to microparticles) that are 'less than 600 nm' (as opposed to at least 600 nm). Therefore, the contents of claim 7 do not provide descriptive support for the limitation now added to claims 1 and 15. Similarly, the fourth paragraph on page 5 provides descriptive support for a method of inducing a T_{H2} polarised immune response to an antigen, the non-elected subject matter. The description in the third paragraph on page 5 of the specification relates to the elected subject matter, but fails to provide descriptive support for the method now claimed in amended claims 1 and 15. This part of the specification does not provide descriptive support for a method of inducing a T_{H1} polarised immune response to an antigen comprising parenteral administration to a subject of microparticles sized such that 'at least 50% of the microparticles are at least 0.6 μ m **and** at least 50% of the microparticles are less than 5 μ m' [Emphasis added]. 'Microparticles' that are 'at least 0.6 μ m' in size are neither supported in the third paragraph nor in the fourth paragraph of page 5 of the instant specification, or in claim 7 which is indeed unrelated to the elected method. A method of inducing a polarized T_{H1} immune response to an antigen by parenterally administering to a subject microparticles with the now recited microparticle size combination is not contemplated in the instant specification, as originally filed. Therefore, the new limitation in the instant claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly

unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitation identified above, or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

13) Claims 1-6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague, indefinite and/or incorrect in the limitation "a least 50% of the microparticles". It is unclear what quantity of microparticles does this limitation encompass.

(b) Claims 2-6, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

14) Claims 1-6 and 15-20 stand rejected.

15) Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the

Serial Number 09/386,266
Art Unit: 1645


Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

17) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November, 2002


S. DEVI, PH.D.
PRIMARY EXAMINER